Premarket Notification [510(K)] Summary

MAR 1 8 2002

(per 21 CFR 807.92)

K020069 1/2

1. Submitted by:

Medtronic Midas Rex
4620 North Beach Street
Fort Worth, TX 76137

Contact Person: Greg Cannedy
Director of Regulatory Affairs
Telephone: 817-788-6400
Facsimile: 817-788-6222

Date Prepared: January 7, 2002

2. Device Name

Trade/Proprietary Name: Midas Rex Legend System
Common/Usual Name: Surgical drill motors with accessories
Classification Name: Pneumatic cranial drill motors for neurosurgery (HBB)
Surgical drill for Ear, Nose & Throat (ERL)
Surgical Ear, Nose & Throat bur (EQJ)
Pneumatic motor for orthopedic surgery (HSZ)
Pneumatic motor for general surgery (GET)
Pneumatically powered saw (KFK)
Powered simple cranial drills, burrs, and accessories (HBE)
Blades, saw, surgical cardiovascular (DWH)

3. Predicate Device:

The Medtronic Midas Rex Legend System is substantially equivalent to the Midas Rex Classic and Midas Rex III Instrumentation Systems, and the Mednext 1000 Bone Dissecting System.

4. Intended use of the device

The Medtronic Midas Rex Legend System is a pneumatically operated surgical instrument system. The pneumatic motor provides power to operate removable rotating surgical cutting tools and their accessories intended for use in neurosurgery, including craniotomy and spinal surgery; as well as Ear Nose and Throat (ENT), orthopedic, and general surgical applications including maxillofacial, craniofacial and sternotomy surgeries.

5. Description of the Device

The Medtronic Midas Rex Legend System is a modular, pneumatic, high-speed instrument system consisting of a motor (handpiece) and accessories/attachments, including but not limited to adapters, spindles, burrs, drills, cutters, and other dissecting tools.

6. Summary of the technological characteristics of the device compared to the predicate device.

The intended use of the Medtronic Midas Rex Legend System have not changed to the intended uses of the Midas Rex Classic, Midas Rex III, and Mednext 1000 systems. The modified device and the predicate devices have the same technological characteristics, the same operating principles, use the same patient contacting materials, and have similar performance characteristics. These systems utilize a high-pressure gas source (either air or nitrogen) to power the motors and drive the cutting tools for use during surgical applications.

7. Testing

Performance testing on the Medtronic Midas Rex Legend System confirms that the device operates as intended, and is substantially equivalent to the Midas Rex Classic, Midas Rex III, and Mednext 1000 Instrumentation Systems.

8. Conclusions

Based upon the testing and comparison to the predicate devices, the Medtronic Midas Rex Legend System performs as intended and raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 8 2002

Medtronic Midas Rex
Mr. Greg Cannedy
Director of Regulatory Affairs
4620 North Beach Street
Fort Worth, Texas 76137

Re: K020069
Trade Name: Midas Rex Legend System
Regulation Number: 882.4370
Regulation Name: Pneumatic Cranial Drill Motor
Regulatory Class: II
Product Code: HBB
Dated: January 8, 2002
Received: January 9, 2002

Dear Mr. Cannedy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K020069

Device Name: Medtronic Midas Rex® Legend™ Instrumentation System

Indications For Use:

The Medtronic Midas Rex Legend System is a pneumatically operated surgical instrument system. The pneumatic motor provides power to operate removable rotating surgical cutting tools and their accessories intended for use in neurosurgery, including craniotomy and spinal surgery; as well as Ear Nose and Throat (ENT), orthopedic, and general surgical applications including maxillofacial, craniofacial and sternotomy surgeries.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use: ✓ (per 21 CFR 801.109) OR Over the Counter Use: (Optional Format 1-2-96)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020069